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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,633	07/17/2003	Marc Long	HO-P02125US1	1856

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,633	LONG ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07/17/03* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment and remarks filed 07/17/03; change of address filed 11/18/03 and IDS filed 02/18/04.

Priority

Examiner acknowledges this application as a divisional of prior application number 09/792,681 filed 02/23/01, now US 6,630,153.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 58-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58 and 86 recite "three-dimensional intricate shaped" and the term intricate shape is confusing.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 58, 59, 62-75, 86-89 and 93-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al. (US 5,614,206).

Randolph teaches a calcium sulfate pellet prepared by mixing alpha calcium sulfate hemihydrate that has a particle size of about 1 μm to about 45 μm, beta calcium sulfate hemihydrate that has a particle size of about 10 μm to about 15 μm (column 2, lines 11-39). Medicaments are mixed with the calcium sulfate in powdered form before mixing (column 4, lines 5-8). Medicaments are antibiotics, chemotherapeutic agents, growth factors, and analgesics. Antibiotics are tetracycline HCl, vancomycin, cephalosporins, tobramycin and gentamycin. Chemotherapeutic agents are cis-platinum, ifosfamide, methotrexate and doxorubicin HCl. Growth factors are transforming growth factors beta (TGF-Beta), bone morphogenic protein (BMP), basic fiberblast growth factor, platelet derived growth factor and other polypeptide growth factor. See column 4, lines 13-28. Pellets are made by molding or pressing (column 4, lines 5-36). Calcium sulfate is bone material and in Randolph it is compressed or molded into pellets; and instant claim 11 recites pellet as one of the shapes. The generic claim broadly compresses granulated bone material into shape. Powder broadly interpreted reads on granules. Randolph anticipates the claims.

5. Claims 58, 59, 63-66, 86-89 and 93-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al. (US 5,981,828).

Nelson teaches cancellous bone chips and cement that is pressed or compacted in a composite allograft press to form composite allograft, and in this case acetabular cup is formed (abstract). The method for forming the acetabular allograft comprises placing the cancellous bone chips in a mold, applying pressure to the bone chips to cause the bone chips to assume the shape of the mold, additional pressure is applied to the mold after an additional bone chips, after adding commercial bone cement

and bone chips, further pressure is exerted on the mold (column 3, lines 26-64, column 4, lines 22-42, column 7, lines 24-30 and claims 1 and 2). The acetabular cup is the shaped bone substitute of Nelson. The compression step in Nelson permits only minimal crushing of the cancellous bone chips (column 7, lines 24-41). Nelson meets the limitations of the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (US 5,614,206).

8. Randolph discloses particle size of about 1 μm to about 45 μm, beta calcium sulfate hemihydrate that has a particle size of about 10 μm to about 15 μm (column 2, lines 11-39). These sizes are not the same as the recited sizes. There is however no demonstration that the recited particle sizes provide unusual results to the bone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the bone graft of Randolph. One having ordinary skill in the art would have prepared particles having sizes of about 1 μm to about 45 μm and of about 10 μm to about 15 μm with the expectation of a controlled release of the medicaments.

9. Claims 90-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 5,981,828).

Nelson teaches the method of the invention except that the prior art teaches a load force of from about 250 to about 500 pounds and teaches against use of loads of 1000 pounds and above (column 7, lines 37-40). This load force lies within the range recited in claims 33-35. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to avoid excessive force as directed by Nelson but apply a force in the range of from about 250 to about 500 pounds making sure not to apply loads of 1000 pounds and above. The expected result would be that the bone chips would not be crushed by optimizing the load force without reaching 1000 pounds and above as taught by Nelson.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yamamoto et al. (US 6,187,046) teaches prosthetic bone material that comprises bonded and sintered product of calcium phosphate granules having particle size of 100 μm (abstract). Methylcellulose is added to hydroxyapatite powder in the formation of granules (example 2). See also column 3, lines 33-54, column 4, lines 2-10, and examples 1-5, 12, 18, 19, 21 and 22.

Laurencin et al. (US 5,626,861) teaches a method for fabricating 3-D macroporous polymer matrices that are used as bone graft or implant and composites are formed from biodegradable and biocompatible polymer and hydroxyapatite calcium phosphate particles (abstract). The biodegradable polymer is lactide-co-glycolide

(abstract). The composite also contains proteins (gelatin or agarose) or starch or polysaccharide (alginate) (column 9, lines 32-38).

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600